

Application Number 10/045,553  
Amendment in response to Office Action mailed May 18, 2004

### **REMARKS**

This Amendment is responsive to the Office Action dated May 18, 2004. In this Amendment, Applicant has amended claims 1, 3, 5, 6, 9-11, 17 and 18, and canceled claims 12-16, 19, and 20. Claims 1-11, 17, 18 and 21 are pending.

### **Examiner's Response to Amendment**

In response to Applicant's previous Amendment filed February 23, 2004, the Examiner stated that it is still not clear how the "gripper" operates. Specifically, the Examiner asserted that the disclosed gripping structure appears to be solid and inflexible, but the term "gripper" used to describe the component implies some form of mechanical movement. Hence, it appears that the Examiner takes issue with the use of the term "gripper" or "gripping" to describe the structure disclosed by Applicant for securing a lead body.

Applicant believes that the term "gripper" or "gripping" is an apt term to describe structure for holding a lead body in place. To alleviate the Examiner's concerns, however, and expedite prosecution toward immediate allowance, Applicant has deleted the terms "gripper" and "gripping" from the claims. The claims have been amended to generally require the use of a channel-like recess, with one or more members that protrude into the channel-like recess, to hold a lead body when the lead body is pushed laterally into the channel-like recess. This amendment should eliminate any possibility of confusion with respect to the terminology in Applicant's claims.

### **Claim Rejection Under 35 U.S.C. § 112, first paragraph**

In the Office Action, the Examiner rejected claims 1-21 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner stated that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and use the invention. In particular, the Examiner stated that it is not clear from the disclosure how the stylet handle "grips and releases the lead body."

Applicant respectfully traverses this rejection. Applicant's disclosure, including the specification and drawings, adequately describes the features set forth in the claims, for purposes of enablement. One skilled in the art of medical lead design would have no difficulty making

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and using the claimed invention without undue experimentation. On the contrary, given the structural embodiments described and illustrated in Applicant's disclosure, those skilled in the art would readily appreciate how to make and use the claimed invention.

To expedite prosecution toward immediate allowance, however, Applicant has amended the claims to clarify the structure of the stylet handle. In particular, as discussed above, the amended claims generally refer to a stylet handle with a channel-like recess, with one or more members that protrude into the channel-like recess, to hold a lead body when the lead body is pushed laterally into the channel-like recess.

A lead body is gripped by placement in channel-like recess, e.g., with a thumb or forefinger, and released by removing the lead body from the channel-like recess. Accordingly, the manner in which a stylet handle grips and releases the lead body is abundantly clear from Applicant's disclosure, particularly as pointed out by Applicant's remarks in the previous Amendment filed February 23, 2004. Moreover, one skilled in the art would have no difficulty making and using such a stylet handle in view of Applicant's disclosure.

At paragraph [0024], for example, the specification indicates that "the lead body 43 is pressed 70 into the lead carrier 56 in the stylet handle 52 by pressing the lead body 43 into the lead carrier 56 using the thumb or forefinger." In this manner, with reference to paragraph [0024], the "lead carrier 56 is designed so a thumb or forefinger has room to push the stimulation lead 40 into the lead carrier 56. By pushing the lead body 43 into the lead carrier 56 the lead body 43 is gripped with at least one gripper 58 in the lead carrier 56."

In addition, FIG. 8 depicts one or more members that protrude into a channel-like recess in lead carrier 56. Upon pressing a lead into lead carrier 56, e.g., with thumb or forefinger, the members that protrude into the channel serve to narrow the channel width and thereby secure the lead body. In view of this disclosure, one skilled in the art would have had no difficulty making and using an embodiment of the claimed invention, including a feature suitable to hold a lead body, as claimed.

With respect to limitations relating to releasing the lead body, Applicant again points out that the claims do not recite such a limitation. Although the embodiment described above would permit release of a lead body, this feature simply is not recited per se by the claims. Nevertheless, just as the lead is pushed into the lead carrier, it can be pulled from the lead carrier.

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Although the claims do not refer to a lead release, some claims do recite a feature of a stylet handle called a "stylet release." According to claim 4, for example, the stylet release has an engaged position where the stylet wire is coupled to the stylet handle and a disengaged position where the stylet wire is decoupled from the stylet handle. According to this limitation, the stylet may be removed from the stylet handle to create a "lead opening."

A lead opening 62 is clearly described in the specification and illustrated in FIG. 9. In an exemplary embodiment, the lead opening 62 permits the stylet handle to be moved toward a lead distal end of the lead body without being encumbered by the stylet wire. In an embodiment described in paragraph [0023], the proximal end of the lead may move through the lead opening 62 in stylet handle 52, allowing the stylet handle 52 to engage the stimulation lead 40 anywhere on the lead body. Therefore, if the Examiner was referring to the "stylet release," it is clear from the specification and drawings that one skilled in the art of lead design would have no difficulty making and using a stylet handle with such a feature.

In view of the depth of detail provided in Applicant's disclosure, one skilled in the art of lead design would be able to readily make and use the claimed invention without undue experimentation. Therefore, Applicant respectfully submits that the disclosure satisfies the enablement requirements of 35 U.S.C. § 112, first paragraph, and request that the Examiner withdraw the rejection of claims 1-21 under 35 U.S.C. § 112, first paragraph.

**Claim Rejection Under 35 U.S.C. § 112, second paragraph**

The Examiner also rejected claims 17-21 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner stated that the term "indentation" implies the existence of a recess rather than a projection and therefore would not "extend" into a channel-like recess. Applicant has amended the claims for purposes of clarification. The amended claims recite one or more "members" that extend into a channel-like recess. Applicant submits that the claims, as amended, particularly point out and distinctly claim the subject matter, as required by 35 U.S.C. § 112, second paragraph.

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**Claim Rejection Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 1-21 under 35 U.S.C. § 103(a) as being unpatentable over Duysens et al. (U.S. 6,104,960) in view of Borkan (U.S. 6,510,347) and Auth (U.S. 4,829,999); rejected claims 17-21 under 35 U.S.C. § 103(a) as being unpatentable over Duysens et al. in view of Borkan and Auth, and further in view of Pillari (U.S. 4,834,708); and rejected claims 1-3, 5-7, 9-17 and 19-21 under 35 U.S.C. § 103(a) as being unpatentable over Duysens et al. in view of Borkan and Loney et al. (U.S. 5,137,517).

Applicant respectfully traverses these rejections, to the extent they may be considered applicable to the claims, as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's amended claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Contrary to the requirements of amended claims 1-4, the applied references fail to disclose or suggest an implantable neurological stimulation lead with an improved stylet handle comprising a lead body, a stylet wire configured for insertion into a stylet lumen in the lead body, and a stylet handle connected to the stylet wire, wherein the stylet handle defines a lead carrier with a channel-like recess to receive the lead body when the lead body is pushed laterally into the channel-like recess, and includes one or more members that protrude into the channel-like recess to hold the lead body at any selected point along the lead body between the body distal end and the body proximal end.

Similarly, with respect to claim 5, none of the applied references suggests an implantable neurological stimulation lead with improved stylet handle comprising a lead body, a stylet wire, and a stylet handle means for holding the lead body at any selected point along the lead body between the body distal end and the body proximal end, wherein the stylet handle means defines a lead carrier with a channel-like recess to receive the lead body when the lead body is pushed laterally into the channel-like recess, and includes one or more members that protrude into the channel-like recess to hold the lead body.

The applied references also lack any teaching that would have suggested a stylet for an implantable neurological stimulation lead comprising a stylet wire, and a stylet handle connected to the stylet wire, wherein the stylet handle defines a lead carrier with a channel-like recess to receive the lead body when the lead body is pushed laterally into the channel-like recess, and

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includes one or more members that protrude into the channel-like recess to hold the lead body at any selected point along the lead body between a distal end of the lead body and a proximal end of the lead body, as defined by claims 6-8.

With respect to claim 9, the applied references also fail to disclose or suggest a stylet for an implantable neurological stimulation lead comprising a stylet wire, and a means for holding a lead body selectively connected to the stylet wire, the means for holding defining a channel-like recess to receive the lead body when the lead body is pushed laterally into the channel-like recess, and including one or more members that protrude into the channel-like recess to hold the lead body at any selected point along the lead body between a distal end of the lead body and a proximal end of the lead body.

Further, contrary to the requirements of claims 10 and 11, the applied references fail to disclose or suggest a method for inserting a stylet in a neurological stimulation lead, comprising inserting a stylet wire into a stylet lumen, stopping insertion of the stylet wire when the stylet wire contacts a stylet stop in the stylet lumen of a lead body distal end, inserting the lead body in a stylet handle lead carrier, and holding the lead body at any selected point along the lead body between a lead body distal end of and the lead body proximal end within a channel-like recess located in the stylet handle lead carrier when the lead body is pushed laterally into the channel-like recess while the stylet wire remains in contact with the stylet stop in the stylet lumen in the lead body distal end, wherein the stylet handle lead carrier further includes one or more members that protrude into the channel-like recess to hold the lead body.

None of the applied references suggests the features of claims 17, 18 and 21, as amended, which recite a device for implanting a neurostimulation lead comprising a stylet wire for insertion into a stylet lumen in a neurostimulation lead, and a stylet handle connected to the stylet wire, the stylet handle having a lead carrier to hold the lead at a selected point along the lead, wherein the lead carrier defines a channel-like recess to receive the lead when the lead is pushed laterally into the channel-like recess, and one or more members that extend into the channel-like recess.

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***Duysens et al./Borkan/Auth***

The Examiner cited Duysens et al. as disclosing "a neurological implant system for locating an electrode in a patient adjacent the spinal column," including "an electrode, stylet wire and a handle 170 for gripping the electrode and wire." The Examiner stated that Duysens et al. does not disclose "the specifics of the electrode and the handle claimed."

The Examiner cited Borkan, however, as disclosing "a spinal cord stimulating lead having electrodes (34, 36), electrical conductor (39), an internal conductor joining those two elements, and a stylet wire." The Examiner stated that in some embodiments the electrode is closed and would form a stop for the stylet wire.

The Examiner also cited Auth as disclosing "a device for gripping a medical lead having a lead carrier (12), a lead gripper (18, 20) and release mechanism (22, 24)." The Examiner further stated that "the device has an open construction that allows it to grip the wire along any point of its length. The surface of portion (18, 20) includes a high friction surface deposited thereon. This structure would create a surface having a large number of very small recesses and projections."

On this basis, the Examiner concluded that it would have been obvious to modify the Duysens et al. device to include an electrode of the type disclosed by Borkan, "to provide a more efficient system." The Examiner further concluded that it would have been obvious to use a "feed of the type disclosed by Auth in place of that disclosed by Duysens et al. . . . given that it provides better control of the elements."

Auth discloses a guidewire gripping device for manipulating a guidewire, but makes no mention of a stylet handle capable of holding a neurostimulation lead as defined by the pending claims. Auth provides no teaching that would have suggested a stylet handle having a lead carrier that defines a channel-like recess to receive the lead when the lead is pushed laterally into the channel-like recess, and one or more members that extend into the channel-like recess.

On the contrary, Auth describes a slitted cylindrical body having a pair of jaws 18, 20 that are spring-biased to clamp onto a guidewire. In particular, handles 22, 24 must be urged together to cause jaws 18, 20 to come apart and thereby permit insertion of a guidewire. The spring bias exerted upon jaws 18, 20 serves to hold the guidewire in placed. The slitted cylindrical body described by Auth does not define a channel-like recess into which a lead body could be laterally

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pushed. On the contrary, handles 22, 24 must be pushed together to open jaws 18, 20 for accommodation of a guidewire. Hence, Auth simply describes a pair of jaws, and not a channel-like recess in a stylet handle, as set forth in Applicant's claims.

Notably, the "gritty" material in the roughened surface described by Auth cannot reasonably be interpreted as members that extend into a channel-like recess of a stylet handle, as claimed. The grit particles would not "hold" a lead body, as claimed. Instead, the spring biased jaws in the Auth device are responsible for holding the disclosed guidewire.

In view of these differences, modification of the Duysens et al. device, as modified by Borkan, to include the features described by Auth would not result in the claimed invention. In particular, the resulting structure would not provide a channel-like recess to receive a lead when the lead is pushed laterally into the channel-like recess, and one or more members that extend into the channel-like recess. Moreover, it would not have been obvious to modify Duysens et al. device according to Auth in the first place. For example, it is unclear how the Auth structure would actually provide "better control" in the Duysens et al. device, and why one of ordinary skill in the art would have looked to the Auth reference.

*Duysens et al./Borkan/Auth/Pillari*

The Examiner cited Pillari as disclosing "a needle assembly having projections 64 that create a frictional surface on the device." On this basis, the Examiner concluded that it would have been obvious to add projections of the type disclosed by Pillari in place of the roughened surface described by Auth to provide "a more defined frictional surface" for the Duysens et al. device. Applicant respectfully traverses this rejection.

Pillari discloses a puncture needle assembly including a plurality of gripping<sup>1</sup> dots 64 that interact with complementary gripping dots 66 to prevent rotation of a stylet within the needle cannula. Pillari merely teaches a frictional surface in a medical device. Pillari makes no mention of the application of gripping dots 64 to grip a neurostimulation lead as defined by the pending claims.

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<sup>1</sup> Applicant notes that Pillari use the term "gripping" in reference to a feature that does not appear to require mechanical movement. This seems to cast some doubt over the Examiner's contention about similar terminology previously recited in Applicant's claims. Nevertheless, this issue should be moot in light of the claim amendments.

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Moreover, Pillari makes no reference to a stylet handle or a neurostimulation lead, nor the desirability of gripping dots 66 to hold lead bodies, guidewires or stylets. One of ordinary skill in the art of lead design would have found no teaching within Pillari that would have suggested modification of the Auth device to include gripping dots 66. Pillari also provides no teaching relevant to a channel-like recess, or any reason why one of ordinary skill in the art would have contemplated the addition of gripping dots, per Pillari, to a channel-like recess.

Pillari simply is not designed to grip a lead or guidewire, and provides no pertinent teaching that would have suggested such applications. Further, it is unclear why one of ordinary skill in the art would have been interested in adding dot-like "projections" to the Auth device, particularly in light of the fact that the Auth device already relies on spring-loaded jaws to hold a guidewire in place. The spring-loaded jaws hold the guidewire at every point along the length of the jaws. Accordingly, the value of adding individual projections, as taught by Pillari, in the Auth device is unclear to Applicant.

Even if the Auth device were modified in view of Pillari, the result would not conform to the requirements of the claimed invention. Specifically, the resulting device still would not have a channel-like recess to receive a lead when the lead is pushed laterally into the channel-like recess, and one or more members that extend into the channel-like recess. Again, Auth requires actuation of handles 22, 24 to hold a guidewire, and does not describe any structure resembling a channel-like recess as claimed.

*Duysens et al./Borkan/Loney et al.*

The Examiner also cited Loney et al. as disclosing "a device for gripping a medical lead having a lead carrier and means to grip (16) the lead body at any point along the lead body." On this basis, the Examiner concluded that it would have been obvious to modify the Duysens et al. device, as modified by Borkan, to use a "feed of the type disclosed by Loney et al. in place of that disclosed by Duysens et al. . . . given that it provides better control of the elements."

Applicant respectfully traverses this rejection, to the extent the rejection may be considered applicable to the claims, as amended. Loney et al. provides no teaching that would have suggested modification of the Duysens et al. device, as modified by Borkan, to include a



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channel-like recess, with one or more members that protrude into the channel-like recess, to hold a lead body when the lead body is pushed laterally into the channel-like recess.

Instead, Loney et al. describes a sliding insert member that slides along a channel to grip a medical shaft. The sliding insert member mounts within the channel and is slidable along a ramp to pinch the medical shaft in place. Loney et al. lacks any teaching of a channel-like recess with one or more members that protrude into the recess to hold a lead body. Accordingly, Duysens et al., Borkan and Loney et al. fail to support a prima facie case of obviousness with respect to Applicant's claims.

### CONCLUSION

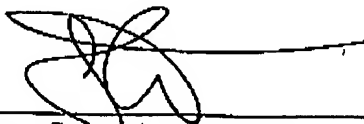
All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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10-18-04

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